4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act". Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure--(OMB Control Number 0910-New)

The draft guidance suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are outside the device's approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or conditions. The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use in order to determine areas where further pediatric device development could be useful. This recommendation applies to applicants who submit the following applications:

1. Any request for a humanitarian device exemption submitted under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m));

2. Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act (21 U.S.C. 360e);

3. Any product development protocol submitted under section 515 of the FD&C Act.

In the Federal Register of February 19, 2013, (78 FR 11654), FDA published a 60-day notice requesting public comment on the proposed collection of information. However, only one comment was interpreted as being related to the proposed collection of information.

One comment stated that FDA should not require all readily available information on pediatric uses of devices because it is unduly burdensome, but rather applicants should be required to perform a reasonable search. FDA disagrees with the comment. In order for FDA to be provided useful, comprehensive information and to fulfill the statutory mandate, all readily available information should be submitted to FDA. Moreover, the requirement is not unduly burdensome because FDA is only requiring all information that is readily available, not all information in general.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Description	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Uses outside approved indication	148	1	148	0.5	74

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814 (21 CFR part 814), subpart B have been approved under OMB control number 0910-0231, and the collections of information in part 814, subpart H have been approved under OMB control number 0910-0332.

Dated: December 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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